

Exhibit 101

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.
Civil Action No. 07-10248-PBS

Exhibit to the July 24, 2009, Declaration of James J. Fauci
In Support of Plaintiff's Motion for Partial Summary Judgment and
In Opposition to the Roxane Defendants' Motion For Partial Summary Judgment

Memo



Palliative Care Sales Team

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Reimbursement Background

September 8, 2000

Enclosed is a *Reimbursement Background* document including a glossary of common pharmaceutical and managed care terms. This document provides a historical review of pharmaceutical pricing and reimbursement issues, along with a review of how retail pharmacies are reimbursed. Knowledge of pharmaceutical reimbursement practices, especially how they may affect pharmacist acceptance for Roxicodone 15mg and 30mg tablets, will play an important part in your successful stocking of these new strengths in your retail accounts after the launch meeting.

Roxane Laboratories, Inc.

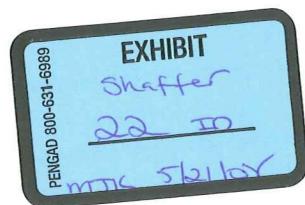
This document should be inserted into your Training Manual, along with Modules I, II, and III, and should be brought with you to the launch meeting on September 18.

Please review this material prior to the meeting. The information in this paper will provide you with a foundation for further discussions at a workshop that will enable you to effectively maximize your retail stocking efforts.

Good Selling!

A handwritten signature in black ink, appearing to read "Mark".

Mark



REIMBURSEMENT BACKGROUND

Introduction

Several factors contribute to the success of a pharmaceutical product during the product life cycle including product attributes, promotion strategy, and the strategy for setting the price and reimbursement. The purpose of this paper is to provide a broad understanding of pharmaceutical pricing and reimbursement issues, especially as they relate to reimbursement at the pharmacy level.

Pharmacy reimbursement will influence the pharmacist's acceptance for the new Roxicodone 15mg and 30mg tablets. Your ability to understand reimbursement issues will assist you in your discussions with your retail accounts to insure a successful stocking program.

Dosage flexibility and reduction of pill burden, for patients suffering from moderate to severe pain, are primary benefits of Roxicodone 15mg and 30mg tablets. Insuring pharmacist acceptance of these new strengths will result in better pain management for a significant number of patients.

Historical Perspective

During the past decade, reimbursement to providers for healthcare products and services has grown increasingly complex and controversial. In very few industries is the process for receiving payment for a product or service as indirect and complicated as it is for healthcare services and products.

In most industries, the recipient of a good or service generally pays the supplier directly for the value which they receive. Prices for these goods and services are often well established allowing the purchaser to make a conscious decision whether to actually order and make payment based on their value perception. Prices and discounts are usually published, transparent, and open to negotiation including discounts for ordering larger quantities, incentives for repeat or immediate purchases, price breaks for bundled arrangements, etc. Unfortunately, many of these characteristics for establishing prices to the purchaser or end user, and for providing payment or reimbursement to the supplier, are not clear, readily transparent, or perceived as fair when discussing healthcare products and services.

Reimbursement for healthcare products and services has evolved from patients paying "out of pocket" to partial or full coverage by insurance companies, and finally to a reimbursement process through a complex web of insurance companies, PBM's (Pharmacy Benefit Managers), employers and government agencies. Health insurance was initially developed by insurance companies to cover non-routine and expensive services such as hospital care and surgical procedures. Providers (physicians, pharmacists and hospitals) were in the unique position of being able to charge a going rate of what the "market would bear" for the services and products that they provided to patients. The ultimate payers – individuals, employers or government

agencies – generally paid for these products or services with little flexibility to negotiate for the perceived value of the product or service which a patient received. Very few payers, with the exception of the federal government and state agencies, were able to develop the ability to negotiate these payments. As healthcare expenditures escalated during the 1970's and 1980's, the federal government and insurance companies (primarily because of increased pressure from employers) set in motion several regulations and processes to limit this exponential increase in healthcare expenditures. The primary emphasis for setting limits on healthcare expenditures during the 1970's and 1980's was on hospital procedures and length of stay; this emphasis then evolved to setting limitations on both in-patient and out-patient services provided by physicians.

By the late 1980's, the emphasis to limit healthcare expenditures progressed to also include setting limitations on pharmaceutical products. Reimbursement limitations for in-patient pharmaceutical expenses were easier to implement because of the previous actions taken to limit hospital expenditures. For out-patient Rx products, managed care organizations, and subsequently PBM's, began to impose restrictions on pharmaceutical products in the late 1980's through a two-pronged attack.

One of their first steps was to request additional price discounts or rebates from pharmaceutical companies for their Rx products. Pharmaceutical manufacturers were forced to comply if they wanted their products readily available for patients belonging to the managed care organization or health plan. Formularies were established by these organizations to enforce this availability. The advent of OBRA-90 (Omnibus Reconciliation Act of 1990) thrust the federal government into implementing major limitations on the coverage and availability of pharmaceutical products to Medicaid patients who received approximately 12% of the Rx's dispensed in the United States. This passage of OBRA-90 provided additional momentum for private payers to seek methods and limitations on pharmaceutical products provided to individuals covered by private health plans. The substantial increase in the availability of generic products during the 1990's, coupled with the increasing introduction of new and innovative pharmaceuticals, heightened the issue of pharmaceutical prices which indirectly focused the spotlight on pharmaceutical reimbursement practices. The second primary step, implemented by payers or their representatives, was to squeeze the pharmacist's profit margin by reducing both their dispensing fees and reimbursement payback for their original purchase of product.

Since over 80% of pharmaceutical purchases are now covered by third-party payers or government agencies, their power to regulate and manage the reimbursement process is huge. As the balance of the uninsured and Medicare patients continue to receive increased public visibility, the strategy set by pharmaceutical companies to effectively price their products for appropriate reimbursement to providers will be as important as the actual price paid by the ultimate payer.

As previously noted, reimbursement in the healthcare arena is primarily twofold – reimbursement to providers for services primarily affects hospitals, physicians, etc., and reimbursement for products primarily impacts the payer and dispenser (i.e., retail pharmacist) for the product. The topic of healthcare reimbursement for services is exceedingly complex requiring an understanding of capitation, DRG's (Diagnosis Related Groups), ICD-9 codes (International Classification of Diseases), conversion factors, RVU's (relative value unit) and a host of other factors.

Although the topic of pharmaceutical reimbursement is not as complex, knowledge of the pharmaceutical reimbursement process, including the effective implementation of a reimbursement strategy, is absolutely essential for the successful introduction and sales growth of any pharmaceutical product. The remainder of this paper will focus on pharmaceutical reimbursement and specifically the reimbursement strategy for Roxicodone 15mg and 30mg tablets.

Pharmaceutical Product Reimbursement

The development of a pricing reimbursement strategy for pharmaceutical products must account for two important considerations which often are mutually exclusive. First, the price paid by the ultimate payer must be considered consistent, fair and reasonable with respect to other alternatives. If the price does not meet the ultimate payer's value perception, they will either pursue guidelines for limiting product usage or will require generic or therapeutic alternatives.

Secondly, a price reimbursement strategy must insure that the pharmacist (the provider of a prescription) is not penalized when compared to possible alternative dispensing options. In other words, the profit dollars earned by the pharmacy, based on the applicable reimbursement formula, must be similar to alternative products so as to prevent the pharmacist from substituting the alternative. As previously mentioned, payers are attempting to maximize their profits by reducing the pharmacist's profit margin as much as possible. A reimbursement strategy that assists the pharmacist in earning an equitable profit should ultimately pay dividends for the pharmaceutical manufacturer.

How did all of this come about and how does reimbursement actually work at the pharmacy level?

Historically, pricing and reimbursement for pharmaceutical products were easy to understand. In an overly simplified version, pharmaceutical manufacturers distributed their products to wholesalers and pharmacies at a published manufacturer's list price. This price may have differed because of the economics of shipping larger volumes to a wholesaler. The WAC (Wholesaler Acquisition Cost) was the list price that pharmaceutical manufacturers charged wholesalers and was often less than the list price to non-wholesale direct accounts. Wholesalers marked up their acquisition cost by 20% -25% for resale to their pharmacy customers. These resale prices were referred to as Average Wholesale Prices (AWP) and were meant to reflect an average of suggested list prices that wholesalers charged various customer outlets (e.g., retail

pharmacies and physician offices). As both wholesaler competition and the buying power of retailers increased through independent buying groups and chain affiliations, their markup to the retail trade decreased to the point that a wholesaler's margin for most products is now only a marginal 1% -2% over their acquisition cost. But the traditional AWP listing, at a markup of 20% - 25% over WAC, has continued to be published as the "official" price for pharmaceutical products.

In addition, as generic manufacturers began to inundate the retail market with their generic versions of previously patented brand name products, they established an AWP as high as possible over their lower direct price so that the pharmacist could still realize the same or greater dollar spread when dispensing the generic product. In other words, the lower priced generic product benefited the payer but not the pharmacist, unless the percentage spread between AWP and the pharmacist's acquisition cost could be increased to compare to the dollar equivalent of the much higher priced brand name product being substituted.

As a result, these pricing scenarios now result in a less than ideal pricing index that is used as a common basis for third-party reimbursement to both pharmacists and physicians. The **pharmacy is reimbursed by the payer based on the formula: AWP less a defined percentage plus a dispensing fee. The difference between the pharmacy reimbursement (AWP less a percentage) and the direct price paid by the pharmacist is the profit margin (spread) which drives the pharmacist to fill a prescription with a particular company's product when other alternatives are allowable and available.**

In addition to the revenue from the profit margin spread, payers generally provide a dispensing fee for each Rx filled. Since the dispensing fee is often only a few dollars, these fees do not begin to cover the labor and overhead expenses in the pharmacy. Thus, the difference between AWP and acquisition cost has become a primary source of revenue for the retail pharmacy. The lower their acquisition price and the higher the AWP, the more incentive the pharmacist has to dispense a particular product. In an attempt to manage the gaming that has taken place with AWP's and reductions off of acquisition price, third-party payers have implemented discounts off of AWP before calculating the reimbursement payment. These discounts may vary from 5% - 20% off of a brand AWP to 10% - 50% off a generic AWP.

In addition to discounted AWP for pharmacy reimbursement, some payers have established a payment schedule on the basis of actual acquisition cost (AAC) plus a fee. However, billing complexities and complicated pricing schemes have made it difficult to accurately determine AAC.

Retailers negotiate with third-party payers to enter into reimbursement arrangements which vary based on the exclusivity and size of the network. Larger retailer networks are generally able to negotiate more favorable spreads and higher dispensing fees. Overall, reduced reimbursement to pharmacy over the last five years has reduced pharmacy gross margins to less than 20% from previous levels of 40%.

For generic products, maximum allowable cost (MAC) is also sometimes used when two or more generics are commercially available. This process allows the payer to set a price for a specific generic medication and determines the maximum amount that will be reimbursed. Many payers rely on the MAC set at the federal level by HCFA (Health Care Finance Administration) for use in the Medicaid system. It is set at 150% of the lowest generally available price for generics.

Third-party reimbursement contracts for generic products are usually negotiated for MAC plus a dispensing fee. Contracts may also include bonuses or fees to the pharmacy for switching branded prescriptions to the generic equivalent where available. Sophisticated retail computer systems, including on-line adjudication messages specific to each patient, can provide the pharmacist with all of this information at the point-of-dispensing. This information will usually include the formulary status, co-payments and deductibles required by the patient's health plan.

Once these contracts are negotiated for reimbursement, then retailers will work with wholesalers and manufacturers to reduce their own product acquisition costs in an effort to increase their profit margins.

How does pricing and reimbursement affect the patient?

Customers using third-party reimbursement to obtain prescriptions most often have partial-payment benefit plans that require a co-payment by the patient. These drug benefit programs usually require a deductible and an identification card designating eligibility. On-line information informs the pharmacist of what should be the cost to the patient. Cash customers generally pay the full price of the prescription determined by AWP plus a usual and customary service fee.

Patients having a third-party payment plan for their prescription are affected by co-payments and deductibles. Co-payments are a monetary amount required at the point-of-sale, which may vary from \$3.00 to \$20.00. Plans may be designed to encourage the use of formulary products or generic products by utilizing a lesser co-pay amount for these choices. Three tier co-pays are becoming a more popular method for payers to influence physicians and patients to choose a lower priced generic when their health plan offers several brand and generic product alternatives in a given therapeutic area.

Deductibles are more often associated with indemnity insurance plans and sometimes with self-insured employer groups, although MCO's and PBM's are initiating such designs as well. The prescription deductible, like any other medical service deductible, requires a designated out-of-pocket expenditure before the pharmacy benefit coverage comes into effect. Some plans may use a combination of deductibles and co-payments. Thus the patient is required to pay the full cost of prescriptions until the deductible is met, and then makes a co-payment for future prescriptions in that calendar year.

Pricing decisions affecting cash paying customers include the commercial success of the product, the duration of therapy and store type, in addition to the AWP. Commercial success influences the cash retail price because high-selling products are often featured by drug retailers at

discounted prices to attract store traffic. This loss leader approach relies on the likelihood that a patient taking these high-volume agents are also using other medications. Thus the retailer will forego profits on the one product to make a return on other patient purchases.

Duration of therapy also influences retail pricing because retailers know that medications used for chronic conditions are more likely to be shopped by consumers, meaning consumers will seek out the lowest price. Retailers will generally be more competitive in their price discounting for these chronic use products.

The type of store can also influence pricing. Chain drug stores are likely to set prices below that of independent pharmacies because their front-end sales volume and market share purchase arrangements will allow it. Mass merchants and supermarkets will usually sell at even lower prices than chain drug stores because their pharmacies are viewed as traffic builders rather than profit centers.

Retail prices are often determined based on the most common package size for a product, usually packages of 100. If a product is available in a larger package, such as 500, and that price is available at a discount, the retail customer will buy the product in 500s. Thus the larger accounts have an advantage when they purchase their products in bulk at discounted prices.

In summary, the following table provides an example of the overall summary of the *pricing flow* for a retail-dispensed outpatient drug:

Wholesale Acquisition Cost (WAC)	=>	Retailer Cost	=>	Patient or Payer Cost
<u>Branded Pharmaceutical</u> Wholesale Acquisition Cost (WAC) from manufacturer: Ex: \$100 less cash discount (2%)	=>	Wholesaler Price to Retailer: "Cost" of \$100 + 1% to 5%	=>	Retail Price to Patient or Payer: "Cost" (either AWP or AWP - %); for example \$120 + fee = \$125
<u>Generic Pharmaceutical</u> Wholesale Acquisition Cost (WAC) from manufacturer: Ex: \$10 less cash discount (2%)	=>	Wholesaler Price to Retailer: "Cost" of (\$10) + 1% to 5%	=>	Retail Price to Patient or Payer: "Cost" (either AWP or AWP - %); for example \$13 + fee = \$18
		OR		
\$10 less cash discount (2%)	=>	"Cost" (\$10) + 1% to 5%	=>	Brand Price less 30% = \$87.50
		OR		
		Contract Cost + Variable % = Net Sell		

Bottom Line Message for Pharmaceutical Manufacturers

The delicate balancing act required by pharmaceutical manufacturers to satisfy both the payer and provider (the pharmacist) is often very difficult. A lower AWP is obviously more attractive to the third-party payer (HMO, PBM, etc.). But unless the spread is considered adequate, the prescription dispenser (pharmacist) may be disincentivized to dispense a product. In fact, pharmacy organizations are refusing to fill prescriptions for patients who belong to certain health plans that have squeezed the pharmacist's margin and dispensing fee to unacceptable levels.

In the case of sole-source brand name products including Roxicodone 15mg and 30mg, this is less of an issue because the pharmacist must dispense the Rx as written. But in the case of multi-source or therapeutic equivalent products, the reimbursement to the pharmacist, as set by the AWP spread, must be comparable or attractive enough so that they neither substitute nor request a physician to change an Rx. (This is an advantage when promoting Oramorph SR.)

Application of Reimbursement for Roxicodone 15mg and 30mg

Pricing for Roxicodone 15mg and 30mg tablets reflects pricing and reimbursement implications. In addition, the approval of these two strengths provide Roxane with the unique advantage of three-year exclusivity for the 15mg and 30mg strengths, although the base 5mg strength will continue to be open to generic substitution.

The objective of the introductory pricing approach is to obtain a high degree of retail pharmacy acceptance. Both the AWP and WAC have been set at levels favorable to the average for the oxycodone class of equivalent number of 5mg tablets. The impact on the pharmacist is that their reimbursement for Roxicodone 15mg and 30mg will, on average, be equivalent or possibly higher on a milligram to milligram basis to their reimbursement level for multiple 5mg oxycodone tablets.

The bottom line message for the sales representative is that if you drive the Rx into the pharmacy, you will not have to be concerned that an Rx for 15mg or 30mg tablets will be substituted with multiple 5mg tablets. Since the 15mg and 30mg tablets received an NDA approval, there will be no generic 15mg or 30mg tablets available for the next three years. And since the pharmacist's reimbursement for Roxicodone 15mg and 30mg will be comparable to filling an Rx of multiple 5mg oxycodone tablets, there will be no incentive to either call physicians to switch the Rx or to automatically fill the Rx with multiple 5mg tablets. In addition, regulations in most states will deter substitution of 5mg oxycodone tablets for one Roxicodone 15mg tablet. This product line extension of Roxicodone 15mg and 30mg tablets is truly a sales rep product!

GLOSSARY OF COMMON PHARMACEUTICALPRICING AND MANAGED CARE TERMS

<u>Acronym</u>	<u>Term</u>	<u>Definition</u>
AAC	Actual Acquisition Cost	The actual price charged to pharmacies, hospitals, and other outlets, exclusive of bottom-line discounts (e.g., a discount for prompt payment), free goods, and various off-invoice rebates. "Actual Acquisition Cost" is used synonymously with "Actual Invoice Price."
AWP	Average Wholesale Price	Neither an average price nor a price charged by wholesalers, this figure is a vestige of earlier times. Few, if any, wholesalers even consider AWP today when pricing their prescription products. It is, however, commonly used by retailers and others who dispense medications as the basis for many pricing decisions including the basis for pharmacy reimbursement. Due to its availability from many sources, the AWP is often used as a surrogate for actual prices when studying prescription price trends. AWP's are usually provided by the manufacturer and published by pricing services, such as First Data Bank and Red Book.
	Capitation	An arrangement whereby a pharmaceutical manufacturer or a pharmacy benefits management company agrees to provide pharmaceutical products at a fixed price per insured person for a defined time period. This method contrasts markedly with the traditional method of pricing for pharmaceuticals, which is based on the type and quantity of medication used.
	Contracted Pharmacy	Chain or independent pharmacy under contract with a managed healthcare plan to provide prescription drugs to plan members, usually for discounted dispensing fees or capitated payments.

	Co-Pay	The portion of the cost of the pharmaceutical product to the covered individual. In its most frequent usage, it refers to the amount paid by the individual to the pharmacist at the point of sale. In this case, the pharmacist bills the 3 rd -Party Payer directly. The Co-Pay may vary by type of drug; differential co-pays for brand vs. generic drugs are especially common. Co-pays payable at the point of sale are usually at a fixed dollar amount, but the co-pay can also be a percentage of the total prescription cost, or it can include the incremental cost of obtaining a brand-name rather than a generic drug.
CPT	Current Procedure Terminology	The American Medical Association developed this numeric coding system to describe physician's services.
	Deductible	Portion of healthcare expenses that a plan member must pay before insurance coverage applies.
DRG	Diagnosis Related Group	Hospital reimbursement method in which the client (an MCO or Medicare) pays the hospital a lump sum for each hospital inpatient admission; the amount of the payment depends on the patient's diagnosis.
	Direct Price	The price paid by retailers, before discounts, for products from those manufacturers who sell directly to non-wholesale accounts, such as retailers, hospitals, private practice physicians and public health clinics.
	Dispensing Fee	Fixed fee paid by an MCO or State Medicaid Agency to a retail pharmacy each time the pharmacy fills prescription for a member patient.

	Ex-Factory Price -or- Ex-Manufacturer Price	Used with different meanings. Sometimes used to refer to published list prices, such as the Wholesale Acquisition Price (WAC) and the Direct Price (DP). At other times it refers to the net price realized by manufacturers, including all discounts and rebates.
FFS	Fee-For-Service	Traditional healthcare payment system in which physicians and hospitals receive a direct payment for their billed charge, either from a patient or an insurance company; physicians in PPOs and IPA model HMOs often operate on a discounted fee-for-service basis because they discount their fees for plan members.
	Formulary	A list of drugs approved for use by a hospital or other medical provider; also, a list of drugs which are reimbursable by a Third-Party Payer.
	Generic Substitution	Substitution of a chemically equivalent duplicate for a branded prescription drug with an expired patent.
	Gross Profit (Margin)	The difference between acquisition or production cost of a product and its selling price. The gross profit margin does not include other costs of doing business.
	Group Model HMO	HMO that contracts with a medical group for healthcare services and compensates the group for contracted services at negotiated rates; the group compensates its physicians and contracts with hospitals for patient care.
HMO	Health Maintenance Organization	Organization that provides or arranges for coverage of specific healthcare services needed by plan members for a fixed, pre-paid premium.

	Indemnity Coverage	Any insurance arrangement whereby the covered individual is reimbursed for all pharmaceutical expenditures for products prescribed by any authorized physician, excluding only those classes of medications which are specified in advance by the plan as being excluded. As in other arenas of healthcare, indemnity coverage has been decreasing as managed-care coverage has increased. Patients with indemnity coverage may receive their benefits at the point of sale, by their paying the pharmacist only a co-pay, or even no co-pay; or, patients may have to pay the pharmacist the full price of the prescription and subsequently file for reimbursement from their healthcare plan.
IPA	Independent Practice Association Model HMO	HMO that contracts with individual physicians who see HMO members plus their own patients; the physicians are members of the IPA but remain independent practitioners with their own offices, medical records, and support staff.
IDC-9-CM	International Classification of Diseases With Clinical Modifications	The diagnosis code is added to CPT codes to describe a patient's diagnoses.
	Managed-Care Coverage	In the context of pharmaceutical usage, any arrangement whereby the insurer or Third Party Payer or other party (e.g., pharmaceutical company) influences or attempts to influence the type or quantity of medication that is used by the patient.
	Managed Healthcare	Healthcare system that influences the utilization and cost of healthcare services; the goal is to provide access to quality, cost-effective healthcare.
	Managed Pharmacy Benefit Program	System in which a managed healthcare plan includes the cost of prescription drugs as a part of healthcare coverage.

	Manufacturer's List Price	Usually intended to be synonymous with the Wholesale Acquisition cost (WAC). Sometimes used in a broader sense to refer to the WAC, the Direct Price (DP) and the Average Wholesale Price (AWP).
MAC	Maximum Allowable Cost	Generally the maximum reimbursement for a pharmaceutical product as determined by a state agency and some private payers, primarily for a product with several generic alternatives.
	Medicaid	State-run assistance program designed to provide healthcare coverage for patients who can't afford it, regardless of age. Under the 1965 Social Security Act, the federal government matches the funds the states use to run their Medicaid programs. Some states have turned the administration of their Medicaid programs over to MCO's.
	Medicare	Federally-subsidized medical insurance program designed to supplement healthcare coverage for patients over 65. Like Medicaid, Medicare was established under the 1965 Social Security Act. In recent years, Medicare administrators have turned to MCOs in an effort to control costs.
	Net Price	Also known as "landed price," this is the price, or revenue, realized by a manufacturer after all discounts have been granted.
	Net Profit (Margin)	The difference in selling price and all costs associated with doing business, allocated on a per-unit basis.
OBRA '90	Omnibus Budget Reconciliation Act of 1990	A law drafted by the Senate Committee on Aging that requires manufacturers to pay rebates to state governments for products used by Medicaid recipients. A rebate is a retroactive discount that is paid after a product has been purchased from a wholesaler or retailer.

	Open Formulary	Virtually all reasonable uses of all drugs is permitted by the medical institution or Third-Party Payer. Even within an Open Formulary, however, the use of certain drugs may be encouraged or discouraged.
	Payers	Generally a reference to "third-party payers" unless the ultimate payer for a prescription at the point-of-service is the patient.
P&T	Pharmacy and Therapeutics Committee	Group of administrators, physicians, and pharmacists that function as an advisory panel regarding the safe and effective use of prescription drugs; creates drug formularies for managed healthcare plans.
PBM	Pharmacy Benefit Management Company	Company that manages drug benefit programs on behalf of managed healthcare plans.
	Pharmacy Margin	The difference between AWP (minus a percentage) and actual acquisition cost to the pharmacy.
PPO	Preferred Provider Organization	Managed healthcare plan that contracts with independent providers who provide services for plan members at discounted rates.
	Provider	Physician or organization (e.g., hospital, nursing home, pharmacy) providing a healthcare service.
	Provider Contracting	Arrangements between managed healthcare plans and providers in which providers agree to provide services for plan members at reduced rates.
	Reimbursement	Payment distributed back to the provider of a product or service, which often is not directly related to their costs or cost of acquisition.
RVU	Relative Value Unit	A Medicare measurement unit that assigns a relative numeric value to each service that a CPT code describes.

	Spread	Refers to the profit margin available to the pharmacist. Can either be calculated as the difference between AWP (minus a discount) and the pharmacy acquisition price or sometimes, more simply, as AWP minus WAC.
	Staff Model HMO	HMO that employs providers directly; providers see members in the HMO's own facilities.
	Therapeutic Substitution	Substitution of one drug for another in the same drug class or, in some cases, in another class; the replacement drug must provide the same clinical outcome or effect as the original drug.
TPA	Third-Party Administrator	Claims processing organization that handles insurance claims and the reimbursement of managed healthcare providers.
	Third-Party Payers	The intermediary between the provider and patient; accepts premium payments from individuals or employers and in turn reimburses providers for their services.
	Universal Formulary	Formulary created by a pharmacy benefit management company from which managed healthcare organizations select drugs that are appropriate for their plans.
UCR	Usual, Customary, and Reasonable	Describes the commonly charged or prevailing fees for health services within a geographic area.
	Utilization	Extent to which enrollees of a managed healthcare plan use healthcare services.
	Utilization Management	General practice of evaluating the necessity, appropriateness, and efficacy of healthcare services, and pharmaceutical products, which can occur before, during, and/or after services are performed.
WAC	Wholesale Acquisition Price	This term denotes the ex-factory charge, before discounts, to the wholesaler.

Assumption A: *Simultaneous launch (standard)*
 Assumption B: *Simultaneous launch (competitive)*
 Assumption C: *Launch trails a competitor* Ipratropium MDI
 Generic Product Launch *Plausible to define as two distinct*

Assumption The launch of generic Ipratropium Metered Dose Inhaler (MDI) will be handled as a standard generic launch. The following steps outline the process that will be followed to achieve a successful launch of the product.

Pricing:

As with all generics, how the product is priced will determine how readily the product is accepted by the market. If the product is priced too high there is a risk that the market will not be penetrated to the level that will be needed to fight future challenges of new competitors. Price the product too low and you run the risk of converting the market to generic too quickly and sacrificing BIC profits as a result. The following guidelines should be followed as the product is priced: AWP should be brand less 10%; WAC should be in a range of 30 to 40% off brand WAC; best contract price should be a minimum of 10% less than brand but no higher than WAC.

Wholesale:

The first order of business is to notify the wholesalers of the upcoming launch of MDI. This will be accomplished through the NWDA sheets, all wholesalers will receive this data via FAX roughly one month prior to launch of the product. The National Account Representatives will contact the National Headquarters for the wholesalers during this time period to secure order entry numbers, and secure initial stocking orders.

At this point the National Account Representatives will present any deals that will be offered. The initial stocking deal that will be offered will be 90 days dating and an initial stocking allowance of 5%. The representatives will try to have all accounts place a corporate buy-in of the product for all Distribution Centers (DCs). The Regional Directors will need to follow up with each DC in their assigned territory to ensure the corporate buy-in has been received, if not the RD will secure the initial order form the DC. It must be noted that some DCs may try to avoid placing an order and want to wait until HQ has placed their order, the delay won't be necessary because each RD will receive the order entry numbers from National Accounts prior to calling on the DC. This number shows that corporate has accepted this product for stocking and an order can be placed.

Warehousing Chains and Mail Order Pharmacies:

This class of trade will be called on by the National Account Representatives after the wholesaler program has been completed. The goal will be to have these accounts warehouse the product. The deal that will be offered to this class of trade will again be 90 days dating and 5% off if they warehouse the product. By having these accounts

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 Assumption C: Launch trails a competitor Generic Product Launch

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